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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/935,717	09/23/1997	MICHAEL CATT	IMIN.P-014	8965

21121 7590 08/28/2003

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EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 08/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory ActionApplication No.
08/935,717Applicant(s)
CattExaminer
PortnerArt Unit
1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Jun 30, 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☒ they raise the issue of new matter (see NOTE below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see attachment

3. ☐ Applicant's reply has overcome the following rejection(s): _____
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____
- Claim(s) objected to: 17, 18, 23, 24, and 28-30
- Claim(s) rejected: 11-30
- Claim(s) withdrawn from consideration: _____
8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____

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Allowable Subject Matter

1. Claims 17-18, 23-24, 28-30 define allowable subject matter but are objected to as depending from a rejected claim but would be allowable if amended to independent claim form and the rejection under 35 USC 112, second paragraph, for reasons of record I paper number 22..
2. Claims dependent upon claims 17-18, 23-24 and 28-30, that would not raise new issues after final, would also define allowable subject matter.

Non-Entry of Supplemental Amendment After-Final

3. While the Supplement Amendment After Final seeks to address issues raised by the initial Amendment After-Final, additional issues were raised in the Supplemental Amendment After Final.
4. For at least the following reasons the amendment of claim 12 submitted June 30, 2003 has not been entered:

Upon consideration of the instant specification, the detection reagent was not defined to be a labeled reagent that “specifically binds to the detection zone”; entry would constitute New Matter as the detection reagent is not defined to being the detection zone but to specifically bind in an assay and is immobilized to an immobilized specific binding agent in the detection zone.

The definitions found for the labeled reagent are as follows:

At page 3, lines 29-35 of the instant specification, the detection reagent was defined:

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“In one embodiment, the assay device is on of the type consisting essentially of a porous carrier strip or the like within a hollow casing and wherein **an assay result is revealed by specific binding of a labelled reagent within a detection zone** of the carrier strip, the presence of the labelled reagent within the detection zone being discernable by the reading device”.

At page 22, lines 1-11, the detection reagent is defined as follows:

“liquid testing device will generally include a porous carrier material, such as a strip, through which applied sample liquid such as urine can permeate and wherein **the assay result occurs by means of specific binding of a detectable material in a precisely-defined region (detection zone) of the carrier**, such as a narrow line or small dot, **containing an immobilized specific binding reagent**. The invention is therefore conserved with ways in which localization of a detectable material in such a detection zone can be determine accurately in a simple cost effective manner.”

The instant specification does not define the detection reagent to bind to the detection zone, but to be immobilized in the detection zone through specific binding to an immobilized specific binding reagent as a result of an assay.

The combination of claim limitations proposed in the Supplemental After Final Amendment defines the claimed kit to comprise an assay device that comprises a detection zone, and a labeled reagent that specifically binds the detection zone. This combination of reagents

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does not evidence original descriptive support in the instant specification and therefore if entered would raise a new issue that would require additional consideration and/or search.

5.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

August 26, 2003


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600